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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/897,309 | 07/02/2001 | Robert B. Odell | P-3946C1C1 | 1739 |

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HOFFMAN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

| EXAMINER | |
|---|---|
| HUYNH, LOUIS K | |
| ART UNIT | PAPER NUMBER |
| 3721 | 15 |

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/897,309 | ODELL ET AL. | |
| | Examiner | Art Unit | |
| | Louis K. Huynh | 3721 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-29 and 33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-29 and 33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2003 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-9, 12-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Ishii (US 3,625,353).

Lawecki discloses a method of producing syringe barrels including the steps of: forming a syringe barrel (126) in a forming device (18), transferring the syringe barrel to an enclosure (10) of class 100 environment (column 3, lines 5-18), cleaning the syringe barrel by directing a stream of filtered air toward the syringe barrel to keep contaminants from setting on the syringe barrel (column 4, lines 22-24), and enclosing the syringe barrel in a second container (128) (column 7, lines 25-28). The method of Lawecki meets all of applicant's claimed subject matter except for a step of sterilizing the syringe barrel after the step of enclosing the syringe barrel in a second container.

However, Ishii teaches a method of sterilizing and storing medical syringe barrel (b) wherein the syringe barrel is packaged in a container (21) and is then sterilized (column 2, lines 60-70) in order to render the syringe barrel immediately available in an emergency and/or to save the trouble of performing any extra sterilizing treatment at the time of use.

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified the method of Lawecki by having provided a step of sterilizing the syringe barrel after the syringe barrel is packaged in the second container, as taught by Ishii, in order to render the syringe barrel immediately available in an emergency and/or to save the trouble of performing any extra sterilizing treatment at the time of use.

With respect to claims 3 and 6, the method of Lawecki includes forming the syringe barrel from glass or plastic (column 3, lines 35-43).

With respect to claims 4, 7, 15 and 18, the method of Lawecki includes filling the container with a desired substance and assemble steps, i.e. lubricating the syringe barrel and stopper, applying tip cap, applying stopper, etc. (column 8, lines 19-29) to complete the assembly of a prefilled syringe (column 2, lines 31-38).

With respect to claims 5 and 12, the forming device (18) in enclosed in the enclosure (10) of class 100 environment.

With respect to claims 8-9, 13 and 14, Lawecki discloses a HEPA filter (50) including an independent blower (column 4, lines 33-41) drawing the air from a class 100,000 environment and delivering a laminar stream of air flow into the enclosure (10) of class 100 environment fully enveloping the syringe (column 4, lines 44-50) to keep contaminants from setting on the syringe (column 4, lines 22-24). Lawecki further discloses that the enclosure of class 100 environment is

operated at a positive minimum of 0.5" w.c. pressure relative to the ambient pressure of the class 100,000 environment in which the enclosure is placed (column 4, lines 51-54). Lawecki also discloses an overhead fixture (114) including an ion bar anti-static assemblies (column 7, lines 9-10) for reducing static charge of the syringe barrel.

4. Claims 10, 11, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Ishii (US 3,625,353) as applied to claim 1 above; and further in view of Logothetis (US 4,521,237).

The modified method of Lawecki includes forming the syringe barrel from glass by (column 3, lines 35-43) which meets all of applicant's claimed subject matter but lacks the specific teaching of heating the a glass tube to a temperature of about 760° to 1100° and annealing the syringe at a temperature of about 560° and the steps of forming the glass syringe barrel.

However, Logothetis discloses a method for forming a glass syringe barrel (1) wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to formed a flange (column 3, lines 57-62), see Figs.1 & 2; the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (column 5, lines 8-14), see Fig.5; the syringe barrel assembly is then heated to an annealing temperature (column 4, lines 24-27).

Therefore, it would have been obvious to a person with an ordinary skill in the art at the time the invention was made to have modified the method of Lawecki by having provided the steps of forming a glass syringe barrel by heating and annealing the glass syringe, as taught by Logothetis, in order to form the glass syringe barrels.

Since the temperature range for heating glass to a pliable state for shape forming and the annealing temperature range are known by those skilled in the art (applicants' specification page 19, lines 19-27); therefore, the temperature range for heating the glass tube is considered to be about 760°C to 1100°C, and the temperature range for heating the glass tube to an annealing temperature is considered to be about 560°C.

5. Claims 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Logothetis (US 4,521,237).

Lawecki discloses a method for producing glass syringe barrels (column 3, lines 35-43) including a step of transferring the glass syringe barrels to an enclosure of class 100 environment in order to maintain a predetermined cleanliness level of the syringe barrels from the time the syringe barrels are fabricated to the time the syringes barrels are placed in sealed containers for shipment (abstract). The method of Lawecki meets all of applicant claimed subject matter except for the detailed process of forming a glass syringe.

However, Logothetis discloses a method for forming a glass syringe barrel (1) on a forming device (column 3, lines 40-43) wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to formed a flange (column 3, lines 57-62; Figures 1 & 2); the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (column 5, lines 8-14; Figure 5); the syringe barrel is then heated to an annealing temperature (column 4, lines 24-27).

Therefore, it would have been obvious to an ordinary skilled in the art at the time the invention was made to have modified the method of Lawecki by having provided a forming

device for forming the glass syringe barrels, as taught by Logothetis, in order to produce glass syringe barrels prior to transferring the glass syringe barrels the enclosure of class 100 environment in order to maintain a predetermined cleanliness level of the glass syringe barrels during the processing of the glass syringe barrels.

With respect to claim 20, the modified method of Lawecki further includes the steps of: applying a tip cap, applying a stopper, etc. to the glass syringe barrel (column 8, lines 19-29) to form a glass syringe assembly; placing the glass syringe assembly in a holder (68) to form an array of eight glass syringe assemblies (column 7, lines 17-21), enclosing the array in a second container (128) (column 7, lines 25-28).

With respect to claim 21, the modified method of Lawecki would include the steps of: supplying a cylindrical glass tube (2) to the forming device; heating the upper end of the glass tube (2) to a pliable state for forming a flange (column 3, lines 57-62; Figures 1 & 2); heating the lower end of the glass tube to a pliable state for shaping the lower end to receive a cannula needle (3) (column 5, lines 8-14; Figure 5).

With respect to claim 22 and 23, since the temperature range for heating glass to a pliable state for shape forming and the annealing temperature range are known by those skilled in the art (applicants' specification page 19, lines 19-27); therefore, the temperature range for heating the glass tube is considered to be about 760°C to 1100°C, and the temperature range for heating the glass tube to an annealing temperature is considered to be about 560°C.

With respect to claims 24 and 25, the modified method of Lawecki would include the step of cleaning the glass syringe by directing a stream of filtered, ionized air toward the glass

syringe to keep contaminants from setting on the glass syringe (column 4, lines 22-24) and to reduce static charge of the glass syringe barrels (column 7, lines 6-10).

With respect to claims 26 and 27, Lawecki discloses a HEPA filter (50) including an independent blower (column 4, lines 33-41) drawing the air from a class 100,000 environment and delivering a laminar stream of air flow into the enclosure (10) of class 100 environment. Lawecki further discloses that the enclosure of class 100 environment is operated at a positive minimum of 0.5" w.c. pressure relative to the ambient pressure of the class 100,000 environment in which the enclosure is placed (column 4, lines 51-54).

With respect to claims 28 and 29, the modified method of Lawecki would include the steps of: transferring the glass syringe barrels to an intermediate isolation module for lubricating the inner surfaces of the syringe barrels (column 8, lines 19-25); and transferring the glass syringe barrels to the packaging isolation module (14).

6. Claims 33, 34, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of AAPA (Applicant Admitted Prior Art).

Lawecki discloses a method of producing plastic syringe barrels including the steps of: forming a plastic syringe barrel (126) in a forming device (18); transferring the plastic syringe barrel to an enclosure (10) of class 100 environment (column 3, lines 5-18); directing a stream of filtered air to clean the plastic syringe barrel (column 4, lines 22-24); delivering a tip cap to the enclosure (10) and assembling the tip cap to the plastic syringe barrel (column 8, lines 19-25); filling the plastic syringe barrel; inserting a stopper (inherent) to the plastic syringe barrel to form a prefilled syringe barrel (column 2, lines 35-38). The method of Lawecki meets all of

applicant's claimed subject matter but lacks the specific teaching of the way the plastic syringe being filled.

However, with regard to the filling of the syringe barrel, AAPA discloses that the syringe barrel can be filled by known method (page 31, line 19 – page 32, line 6). For example, the U.S. 5,620,425 to Heffernan et al. teaches a method for filling a syringe barrel through the open tip end, the U.S. 5,597,530 to Smith et al. teaches a method for filling a syringe barrel through the open bottom end.

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified filled the plastic syringe barrel using a suitable method of either through the proximal end or through the distal end of the plastic syringe barrel, as taught by AAPA, in order to form a prefilled syringe barrel.

With respect to claims 34 and 38, the modified method of Lawecki would include a step of packaging the prefilled syringe barrels.

With respect to claims 35, 36, 39 and 40, AAPA through the references to Heffernan et al. (US 5,620,425) and to Smith et al. (US 5,5,97,530) teaches that the prefilled syringe barrels are sterilized before they are labeled and packaged for use (Heffernan, column 7, lines 11-14; Smith, column 6, lines 26-44). Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified the method of Lawecki by having included the step of sterilizing the prefilled syringe barrels prior to the step of packaging, as taught by AAPA, in order to produce sterilized prefilled syringe barrel packages ready for use.

***Response to Arguments***

7. Applicant's arguments with respect to claims 1, 3-29 and 33-40 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (703) 306-5694. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (703) 308-2187. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Louis K. Huynh
Patent Examiner
Art Unit 3721

LH
July 7, 2003